K070868

510(k) Summary

Submitter's Information

MAY 15 2007

Submitted by MEDIAN Technologies
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Date summary was prepared: May 9, 2007

Name of Device

Proprietary name: LMS-Lung/TRACK
Common name: Lung nodule visualization and analysis software package
Classification Name: Class II, 21 CFR 892.2050, LLZ

Predicate Devices

Manufacturer	R2 Technology, inc.	Philips medical systems	AccuImage Diagnostics Corporation
Trade Name	CA-1500	Lung nodule assessment and comparison option	Primelung
510(k) Number	K040028	K023785	K024149

Device Description

LMS-Lung/TRACK provides visualization and analysis tools for chest CT images acquired in low or normal dose.

LMS-Lung/TRACK segments pulmonary lesions identified by the user with a double click (seed point). Once a lesion is segmented, the software computes its characteristics

such as size, volume and intensity. Alternatively, the user can do its own 2D measurements on the lesion.

LMS-Lung/TRACK matches and compares lesions identified by the physician present in two different datasets of the same patient acquired at different dates. It computes the differences of volume and diameters and volume growth.

LMS-Lung/Track provides tool to generate report with snapshots, and results.

Intended use

LMS-Lung/TRACK is intended to provide the radiologists and other clinicians qualified to interpret CT images the ability to

- visualize chest CT datasets acquired in low or normal dose;
- mark and automatically/manually measure characteristics (such as diameter, volume) of lung nodules selected by the user;
- compare chest CT scans of the same patient over time for quantification of pulmonary lesion evolution (volume growth and doubling time estimation)
- generate automatic reports.

LMS-Lung/Track device is designed to be used in diagnostic thoracic CT examinations in adult patients.

LMS-Lung/Track is not intended to be used for patients with prior thoracotomy.

Substantial Equivalence Comparison Chart

Manufacturer	**R2Technology**	**Philips Medical Systems**	**AccuImage Diagnostics Corporation**	**MEDIAN Technologies**
Product Name	CA-1500	Lung nodule assessment and comparison option	Primelung	**LMS-Lung/TRACK**
510(k) Number	K040028	K023785	K024149	[redacted]
CT scans of lungs as Input	√	√	√	√
Interactive 2D and 3D visualizing tools	√	√	√	√
Segmentation of lung lesions (i.e. boundaries detection)	√	√	√	√

Manufacturer	R2 Technology	Philips Medical Systems	AccuImage Diagnostics Corporation	MEDIAN Technologies
Product Name	CA-1500	Lung nodule assessment and comparison option	Primelung	**LMS-Lung/TRACK**
Extraction and computation of lesion characteristics (2D and 3D)	√	√	√	√
Manual measurement	√	√	√	√
Lesion matching over time	√	√	√	√
Lesion comparison over time	√	√	√	√
Report Generator	√	√	√	√

Safety

A comprehensive hazard analysis was carried out on MEDIAN Technologies' LMS-Lung/TRACK software. It concluded that residual risks were acceptable when weighed against the intended benefits of the system.

Conclusion

LMS-Lung/TRACK software does not raise new safety risks and is equivalent in function to existing legally marketed devices. LMS-Lung/TRACK software is therefore substantially equivalent with respect to safety and effectiveness to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Median Technologies
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MAY 15 2007

Re: K070868
Trade/Device Name: LMS-Lung/TRACK
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ and JAK
Dated: March 26, 2007
Received: March 29, 2007

Dear Mr. Burr:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _K070868__

Device Name: _LMS-Lung/TRACK_____

Indications for Use:

LMS-Lung/TRACK is intended to provide the radiologists and other clinicians qualified to interpret CT images the ability to:

- visualize chest CT datasets acquired in low or normal dose;
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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070868